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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,484	01/23/2002	Keith Alan Foster	1581.0870000/RWE/MTT	2134

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,484	FOSTER ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03/29/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-53* is/are pending in the application.

4a) Of the above claim(s) *54-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's revised election *with* traverse of Group III, now claims 48-53, and now as drawn to "methods for modulating C-fibre neuron activity by administering a *lectin* (as opposed to a lectin conjugate as originally elected), AND the lectin species election of *Erythrina cristagalli* lectin (ECL), in the paper filed 03/29/2006, is acknowledged. The claims have only been examined as drawn to the elected invention, namely a method of inhibiting/stimulating C-fibre activity (and associated diseases/conditions thereto) using a lectin (e.g. comprising the administration of an active agent, wherein said active agent is selected from the group consisting of any lectin alone (e.g. elected species ECL)).

I. Background:

In order to clarify the record on this lengthy prosecuted/examined application, the Examiner notes that the present action is being sent following:

1. Non-Responsive (re: failure of Applicant to make final election, as required) mailed 11/29/05;

2. Second action NON-FINAL rejection (as to therein elected conjugates; following previous restriction and first action on the merits) which was sent on 12/16/04. Applicant's response of 9/28/05 to the Action of 12/16/04 was delayed based on the Office-rendered delay while finalizing the Petition Decision mailed 08/24/05.

The Examiner, under the circumstances surrounding this application and in the interests of customer service (especially in regard to delay on the Petition response and

resolution of the application), has allowed Applicant to change the elected invention mid-prosecution. This has been afforded, based on Applicant's general assertion of confusion over the original restriction requirement (to which a specific conjugate was elected, and then filed a Petition re: Original Restriction, which was as noted denied). Applicant originally elected a conjugate, but shortly thereafter indicated through various telephonic discussions, that the methods as drawn to a lectin (alone) was the desired invention.

II. Returning to Response to Present Election:

The present traversal is once again (and still generally) on the ground(s) that the Examiner misconstrued what the special technical feature (i.e. medicinal lectins). First and foremost, any general lectin is claimed. Not some uniquely structured "medicinal lectin(s)". Apply also argued that at least Groups IV-VI and X should be rejoined. This is not found persuasive because as stated in the Office Action of 1/29/04, at page 6, even if "a lectin is the special technical feature, a lectin alone *does not (did not)* run through every [originally presented] invention claimed . . . [t]hus, there is no special technical feature among Groups I-X and they lack unity". [Applicant appears to back this argument by asserting that ALL lectins are coextensively searchable as having a "lectin fold" which contains "the Asp-Gly-Asn triad". However this is also unpersuasive since this is not a triad at all, namely Applicant's Affidavit reference to Svensson et al., page 2, simply shows that two lectins (ECL and EcorL) happen to contain Asp at residue 89, Gly at residue 107 and Asn at residue 133. Nevertheless, the Examiner IS attempting to search the genus of lectins, and currently only requiring a species

election]. Thus, as previously discussed, lectins versus conjugates, (and arguably lectins versus lectins as discussed above) even if containing lectins therein, are distinct compounds. Therefore, a search of more than Group III would pose an undue burden. *Furthermore, Applicant has already Petitioned the Restriction requirement, and been denied, per the Petition Decision.* Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II or III, restriction for examination purposes as indicated is proper. The requirement is still deemed proper and is therefore made FINAL.

Claims 54-75 are withdrawn as being drawn to non-elected subject matter. Claims 48-53 are examined on the merits.

Claim Objections

Claims 48-53 are objected to because of the following informalities: the recitation of "first" lectin in e.g. claim 48 and 52 renders the claims confusing, since there is no "second" lectin ever claimed. Assuming there is support to simply describe the invention by the term "lectin" alone, it is suggested that "first" simply be omitted. Appropriate correction is required.

35 U.S.C. 112, 1st Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

The claimed invention is primarily drawn to use of any lectin or species Erythrina cristagalli lectin (ECL) alone to inhibit or stimulate C-fibre activity in order to treat any disease or condition resulting from inhibition or stimulation of C-fibre activity.

One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the claimed invention, namely inhibiting/stimulating any C-fibre neuron activity/associated diseases/conditions by any lectin/ECL alone (other than 1 specific conjugate,

as described in more detail below). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116). Namely, the specification has adequately described the use of a single ECL conjugate (e.g. the conjugation of ECL to the clostridial enzyme designated LH_N/A (See Example 3)), in a method of treating two (2) C-fibre associated diseases or conditions: pain (i.e. analgesic affect in mouse, See Figure 3 and Example 5 and 6) and inflammation (pretreatment stimulated rat paw, See Figure 13 and Example 18). However, there is no description as to how or whether any lectin/ECL alone (or any other conjugate for that matter) would be able to inhibit or stimulate any C-fibre neuron activity/diseases or conditions thereto. One of skill in the art would not recognize from the disclosure that the Applicant was in possession of a method of inhibiting or stimulating C-fibre neuron activity/associated diseases or conditions using a lectin/ECL alone.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

35 U.S.C. 112, 1st Scope of Enablement

Claims 48-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating the C-fibre neuron associated diseases/conditions of pain and inflammation by 1 specific ECL *conjugate* (Figures 3 and 13); does not reasonably provide enablement for treatment (e.g. inhibition or stimulation) of any C-fibre neuron associated diseases/conditions by any lectin alone or the elected species ECL alone. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

> The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for treatment of any C-fibre neuron associated diseases/conditions by any lectin for the following reasons:

The nature of the invention: The elected invention is drawn to the use of any lectin or species Erythrina cristagalli lectin (ECL), alone, to inhibit or stimulate C-fibre neuron activity in order to treat any disease or condition resulting from inhibition or stimulation of C-fibre activity.

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). A search of the prior art, as to lectins/ECL for treating C-fiber neuron related disorders, revealed there is a very limited number of teachings directed to the specific invention of the present application. *Therefore, the use of lectins/ECL for inhibiting/stimulating C-fibre neuron associated disorders cannot be construed as being well known in the art, and thus reliance for enablement must stem from the specification.* The specification and claims have adequately described the use of a single ECL *conjugate* in a method of treating two (2) C-fibre associated diseases or conditions: pain (i.e. analgesic affect in mouse, See Figure 3) and inflammation (pretreatment stimulated rat paw, See Figure 13). HOWEVER, there are no working examples to indicate whether any lectin/ECL ALONE, would be enabled for treating ANY C-fibre neuron disease/condition (e.g. pain, inflammation, psoriasis and mucus hypersecretion). One of skill in the art would not recognize from the disclosure that inhibition/stimulation of C-fibre neuron activity and associated diseases/conditions, was enabled using any lectin/ECL alone.

The breadth of the claims and the quantity of experimentation needed: The claims are drawn broadly to the use of ANY lectin/ECL alone in a method for inhibiting/stimulating C-fibre neuron activity generally and associated diseases/conditions. Absent sufficient teachings in the specification or art sufficient to overcome the teachings of unpredictability in the art as to

enablement on whether C-fibre neuron activity or associated diseases/conditions may be inhibited/stimulated using any lectin/ECL alone it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 48-53, it is unclear what the invention is. Namely, Applicant's elected invention is a method of treating a disease or condition resulting from an inhibition or stimulation of C-fibre neuron activity, by modulating C-fibre activity, comprising administering an effective amount of an Erythrina cristagalli lectin conjugate (claim 1); wherein said conjugate may inhibit (claim 40) or stimulate (claim 41) C-fibre activity. It is unclear how an Erythrina cristagalli lectin can both inhibit and stimulate C-fibre activity, in order to treat a disease or condition resulting from an inhibition or stimulation of C-fibre neuron activity? Applicant is asked to point out where in the specification support may be found for both types of modulation by an Erythrina cristagalli lectin, or amend the claims to more distinctly claim the invention. It is suggested that Applicant positively/expressly claim the invention to be either inhibiting or stimulating C-fibre neuron activity, by a/any specific lectin(s) (as long as there is support

thereof); or clearly explain how the same lectin can accomplish both methods (and if the latter, claiming e.g. range amounts to carry out the same).

Prior Art Made of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Oldham et al. (US 2002/0137674) teaches the use of lectins (e.g. Erythrina cristagalli; e.g. Table 1) for the treatment of organisms such as H. Pylori and associated ulcers thereto (para 37). Although ulcers are associated with inflammation (which Applicant describes as one of the C-fibre neuron diseases or conditions), the method of Oldman et al. is directed to treatment of infection (as opposed to C-fibre neuron associated) based ulcers/inflammation. Thus, Oldman et al. is not at this time deemed to reasonably teach or suggest a method of treating (inhibiting/stimulating) C-fibre neuron activity.

Conclusion

Applicant's amendment to the claims and election of the invention (namely, amendment of the elected invention/claims thereto, to a lectin alone (e.g. elected species, Erythrina cristagalli lectin (ECL or ECA)); as opposed to the specific lectin conjugate thereto) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 06/20/2006

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